IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

REED SMITH LLP
225 Fifth Avenue
Pittsburgh, PA 15222

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Avenue
Silver Spring, MD 20993

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiff Reed Smith LLP ("Reed Smith") alleges as follows:

Nature of the Action

1. This is an action brought pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, and under the Administrative Procedure Act ("APA"), 5 U.S.C. § 500, *et seq.* Reed Smith seeks disclosure of agency records designated in a FOIA request it submitted to the Food and Drug Administration ("FDA") on December 20, 2018. FDA has wrongfully withheld such records.

Jurisdiction and Venue

2. This Court has jurisdiction pursuant to FOIA, 5 U.S.C. § 552(a)(4)(B), and 28 U.S.C. § 1331.

3. Venue is proper in this District under 5 U.S.C. § 552(a)(4)(B).

The Parties

4. The Plaintiff, Reed Smith, is a limited liability partnership organized under the laws of the State of Delaware.

5. Defendant FDA is an agency that functions under the authority of Department of Health and Human Services ("HHS"). FDA is an "agency" subject to the requirements of FOIA, 5 U.S.C. § 552(f)(1), and the APA, 5 U.S.C. § 551(1).

Relevant Facts

6. As part of its representation of a client, Reed Smith submitted a FOIA request to Defendant on December 20, 2018, that is the basis of this action. As of the date of this filing FDA has failed to reply to the request as required by FOIA.

7. The FOIA request that forms the basis of this action (the "Request") was submitted to the Division of Freedom of Information of FDA by letter from Rick Robinson and Andrew C. Bernasconi of Reed Smith, dated December 6, 2018 (**Exhibit A**). On December 13, 2018, FDA sent correspondence to Reed Smith acknowledging receipt of the Request and requesting submission of a signed release from Reed Smith's client (**Exhibit B**). The client submitted the appropriate release by letter dated December 14, 2018 (**Exhibit C**). Reed Smith subsequently resubmitted the Request on December 20, 2018 and received confirmation of receipt (FDA1849305) (**Exhibit D**).

8. The Request sought copies of the following agency records:

(a) All FDA Form 482 documents relating to the investigation that included an interview of Steven L. Higgins, MD, on April 13, 2010, at Scripps Memorial Hospital in La Jolla, California at or about 10:20 a.m., by Scott K. Zika, FDA Consumer Safety Office, and Robert S. Sweeton, FDA

Consumer Safety Office (the "2010 Investigation"). Dr. Higgins has disclosed the Form 482 corresponding to his interview, as well as electronic correspondence preceding that interview in which Mr. Zika indicated an interest in discussing Dr. Higgins' awareness of any product quality problems encountered during pacemaker implantation or any product quality problems that would necessitate explantation of pacemakers. Dr. Higgins has thus generally described his interview on April 13, 2010, and his vague understanding of the purpose of the 2010 Investigation, but his memory of the interview and discussions with Mr. Zika and/or Mr. Sweeton were very limited.

(b) Documents relating to the 2010 Investigation, including but not limited to documents concerning Boston Scientific Corporation (including but not limited to its predecessor, Guidant Corporation) and its Cognis and/or Teligen products; transcripts or notes of interviews relating to Boston Scientific/Guidant and Cognis/Teligen; and documents reflecting facts, information, and data provided to FDA in any format (including verbally) during the 2010 Investigation.

(c) Documents reflecting the purpose of the 2010 Investigation, and the basis for initiating the 2010 Investigation, including without limitations notes, memoranda, and reports by Mr. Zika, Mr. Sweeton, or other FDA personnel.

(d) Documents provided to Mr. Zika, Mr. Sweeton, and/or FDA during the 2010 Investigation concerning Boston Scientific Corporation (including

but not limited to its predecessor, Guidant Corporation) and its Cognis and/or Teligen products, including without limitation documents provided by Dr. Higgins and Boston Scientific/Guidant.

(e) Documents reflecting final determinations or conclusions reached by Mr. Zika, Mr. Sweeton, and/or FDA concerning Boston Scientific Corporation (including but not limited to its predecessor, Guidant Corporation) and its Cognis and/or Teligen products in connection with the 2010 Investigation, including closing memoranda, final dispositions, and/or communications reflecting decisions to conclude the 2010 Investigation and reasons therefor.

(f) To the extent not otherwise covered by Request Nos. (a)-(e) immediately above, documents reflecting communications between FDA and Boston Scientific Corporation (including but not limited to its predecessor, Guidant Corporation) concerning defects, recalls, or actual or potential compliance (or lack thereof) of the Cognis and/or Teligen products with FDA rules, procedures, or regulations.

(g) To the extent not otherwise covered by Request Nos. (a)-(f) immediately above, documents containing or reflecting FDA conclusions, determinations, discussions, and decisions concerning the adequacy of the July 2009 recalls of the Boston Scientific/Guidant Cognis and/or Teligen products.

9. Pursuant to 5 U.S.C. § 552(a)(6)(A)(i), FDA had twenty working days in which to comply with the Request. Additionally, according to FDA's administrative regulations, the

agency should have made the determination within twenty working days. 21 C.F.R. § 20.41(b). To date, FDA has not made the determination nor has it claimed any exemption from disclosure.

10. On March 6, 2019, Sandra Williams, an Information Disclosure Officer of the Defendant, sent a letter to Reed Smith explaining that the Division of Information Disclosure Policy – Los Angeles District of the Office of Regulatory Affairs of the Food and Drug Administration was unable to locate any records responsive to the Request at the Los Angeles District Office (**Exhibit E**). As a result, the Request was forwarded to the FDA's Center for Devices and Radiological Health ("CDRH") to conduct a search for the records.

11. On May 3, 2019, Reed Smith sought an update on the status of the Request from Claire Stansbury, a Government Information Specialist with the Division of Freedom of Information of FDA (**Exhibit F**). On May 6, 2019, Ms. Stansbury replied that the Request was still pending with the "Center for Medical Devices." On June 20, 2019, Reed Smith again sought an update from Ms. Stansbury on the Request. On June 25, 2019, Ms. Stansbury replied in pertinent part as follows:

> You have rec'd a partial response from one of our district offices stating ["]No records response.["] You should have rec'd a response letter from them. They closed your request on 3/6/19. It is still pending in our Center for Medical Devices. It is in the complex que. Whoever it is assigned to could have 50 to 100 request a head of yours. They can't take your request out of turn. When your request comes up in the[] que they will start to work on it.

Reed Smith replied asking for a way to expedite the review but Ms. Stansbury replied that only "if it is a life and death situation." *See* Exhibit F.

12. Nothing further has been communicated by FDA to Reed Smith. Now twenty days from our last correspondence confirming our desire to receive the information requested, and over six months since the date of the initial FOIA submission, Reed Smith has yet to receive a response to its request.

13. Despite having had the Request in its possession since at least December 20, 2018, FDA has failed to make a determination as to whether to comply with the Request as required by the FOIA. Because FDA failed to comply with the time limits mandated by statute and regulation, Reed Smith is deemed to have exhausted its administrative remedies. 5 U.S.C. § 552(a)(6)(C)(i).

Count 1: Violation of FOIA

14. An agency may withhold records responsive to a FOIA request only if the agency can prove that the records fall within one of the nine narrow exceptions to mandatory disclosure outlined in the FOIA. Any reasonably segregable portion of a record must be provided, along with an indication of the amount of information withheld from the record. 5 U.S.C. § 552(b). The agency has the burden to demonstrate that any withholding of records was proper and in accordance with the enumerated exceptions. 5 U.S.C. § 552(a)(4)(B).

15. Defendant has violated the FOIA by failing to timely and properly respond to Reed Smith's FOIA request and by improperly withholding agency records responsive to the request.

Count 2: Violation of ADA

16. Furthermore, Defendant has violated its administrative regulations promulgated pursuant to FOIA. *See* 21 C.F.R. § 20.40, *et seq.* (FDA regulations); 45 C.F.R. § 5.1, *et seq.* (HHS regulations).

17. Defendant has violated the APA by acting arbitrarily and capriciously in its failure to respond to Reed Smith's FOIA request and by withholding of documents responsive to that request.

Prayer for Relief

18. WHEREFORE, Reed Smith respectfully requests that this Court:

(a) Declare that the actions of Defendant are unlawful and in violation of applicable provisions of FOIA, the APA, and the agency's administrative regulations;

(b) Enjoin Defendant from continuing to improperly withhold any and all agency records sought by Reed Smith's FOIA request and order the agency to produce to Reed Smith all records improperly withheld;

(c) Award Reed Smith its reasonable attorneys' fees and other costs as authorized by 5 U.S.C. § 552(a)(4)(E); and

(d) Grant such other relief as the Court may deem just and appropriate.

Respectfully submitted,

REED SMITH LLP

By: */s/ James F. Segroves*

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